

Notice of Allowability

Application No.

10/521,193

Examiner

L. E. Crane

Applicant(s)

FISHMAN ET AL.

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed October 2, 2007.
2. ☒ The allowed claim(s) is/are 11,12,14 and 15.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

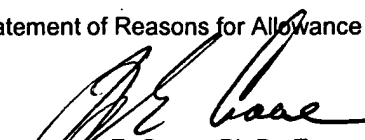
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 12062007.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600

Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

The disclosure was amended by introduction of the following at page 1, before the first line:

-- This is a 371 of PCT/IL04/01160, filed on December 23, 2004 which claims the benefit of US provisional application Serial No. 60/532,712, filed December 29, 2003. --.

At page 5, line 19, the term "fururyl" was amended to read -- furfuryl --.

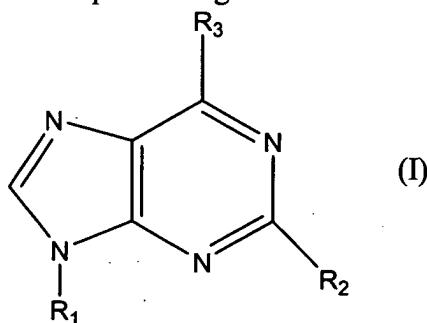
At page 5, line 25, the term "amine" was amended to read -- imine --.

The claims were amended as follows:

Claim 13 was cancelled without prejudice to the filing of a divisional or continuing application.

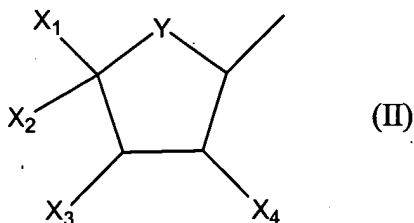
Claims 11, 12, 14 and 15 have been replaced in their entirety by the following:

-- 11. A method for treating an individual suffering from multiple sclerosis (MS) comprising administering to said individual an A₃ adenosine receptor agonist (A₃RAg) wherein said A₃RAg is a compound within the scope of the general formula (I):



wherein,

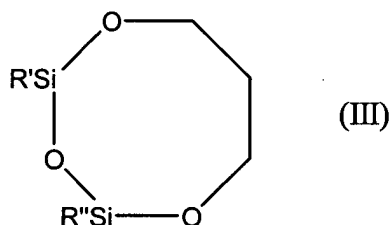
- R_1 represents an alkyl, hydroxyalkyl, carboxyalkyl or cyanoalkyl or a group of the following general formula (II):



in which:

- Y represents an oxygen, sulfur or CH_2 ;
- X_1 represents H, alkyl, $R^a R^b NC(=O)-$ or HOR^c- , wherein
 - R^a and R^b may be the same or different and are hydrogen, alkyl, amino, haloalkyl, aminoalkyl, BOC-aminoalkyl, or cycloalkyl or are joined together to form a heterocyclic ring containing two to five carbon atoms; and
 - R^c is alkyl, amino, haloalkyl, aminoalkyl, BOC-aminoalkyl, or cycloalkyl;
- X_2 is H, hydroxyl, alkylamino, alkylamido or hydroxyalkyl;
- X_3 and X_4 represent independently hydrogen, hydroxyl, amino, amido, azido, halo, alkyl, alkoxy, carboxy, nitrilo, nitro, trifluoro, aryl, alkaryl, thio, thioester, thioether, $-OCOPh$, or $-OC(=S)OPh$ or both X_3 and X_4 are oxygens connected

to $>C=S$ to form a 5-membered ring, or X_2 and X_3 form the ring of formula (III):



where R' and R'' represent independently an alkyl group;

- R_2 is hydrogen, halo, alkylether, amino, hydrazido, alkylamino, alkoxy, thioalkoxy, pyridylthio, alkenyl, alkynyl, thio, or alkylthio; and

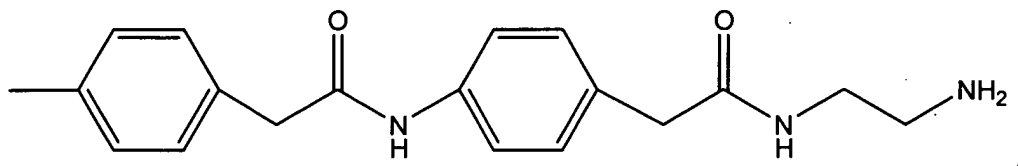
- R_3 is a group of the formula $-NR_4R_5$, wherein

- R_4 is a hydrogen atom or alkyl, substituted alkyl or aryl- $NH-C(Z)-$, with Z being O, S, or NR^a with R^a having the above meanings;

with the proviso that when R_4 is hydrogen then

- R_5 is an R- or S-1-phenylethyl, benzyl, phenylethyl or anilide group, unsubstituted or substituted in one or more positions with a substituent that is alkyl, amino, halo, haloalkyl, nitro, hydroxyl, acetoamido, alkoxy, or sulfonic acid or a salt thereof; benzodioxanemethyl, fururyl, L-propylalanylaminobenzyl, β -alanylaminobenzyl, T-BOC- β -alanylaminobenzyl, phenylamino, carbamoyl, phenoxy or cycloalkyl; or R_5 is a group of the following formula:

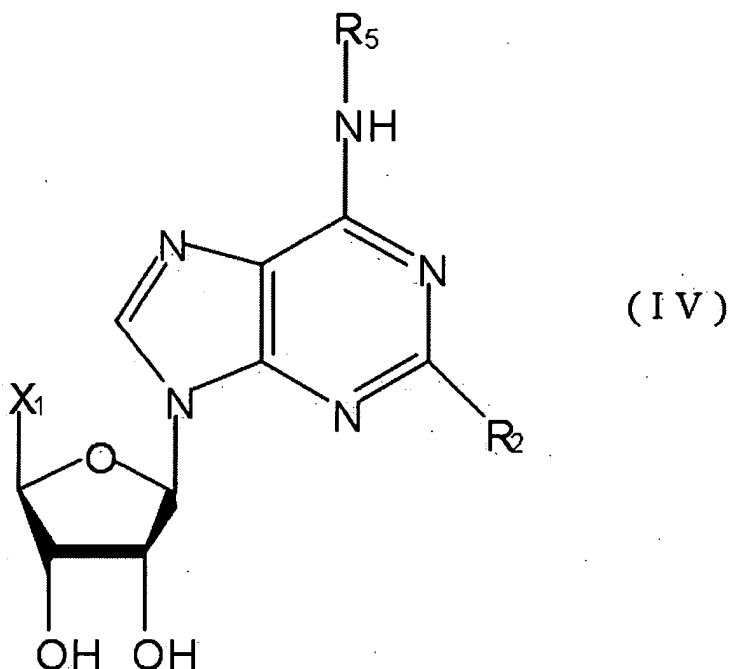
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And with the further proviso that when R_4 is an alkyl or aryl- $NH-C(Z)-$, then, R_5 is heteroaryl- $NR^a-C(Z)-$, heteroaryl- $C(Z)-$, alkaryl- $NR^a-C(Z)-$, alkaryl- $C(Z)-$, aryl- $NR-C(Z)-$, or aryl- $C(Z)-$, Z representing an oxygen, sulfur or imine; or a physiologically acceptable salt of the above compound. --.

-- 12. The method of Claim 11, wherein said A_3Rag is orally administered. --.

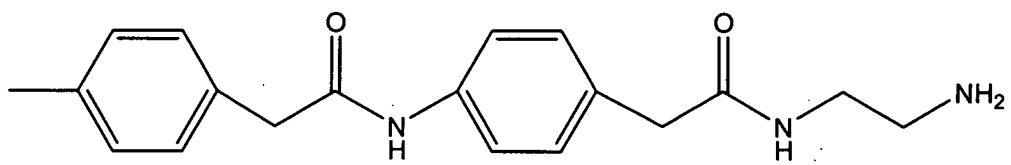
-- 14. The method of claim 11, wherein said A_3Rag is a nucleoside derivative of the general formula (IV):



wherein,

- X_1 represents H, alkyl, $R^a R^b NC(=O)-$ or HOR^c- , wherein
 - R^a and R^b may be the same or different and are hydrogen, alkyl, amino, haloalkyl, aminoalkyl, BOC-aminoalkyl, or cycloalkyl or are joined together to form a heterocyclic ring containing two to five carbon atoms; and
 - R^c is alkyl, or cycloalkyl;
- R_2 is hydrogen, halo, alkylether, amino, hydrazido, alkylamino, alkoxy, thioalkoxy, pyridylthio, alkenyl, alkynyl, thio, or alkylthio; and

- R_5 is an unsubstituted or substituted in one or more positions with a substituent that is alkyl, amino, sulfonic acid or a salt thereof; benzodioxanemethyl, furfuryl, L-propylalanylaminobenzyl, β -alanylaminobenzyl, T-BOC- β -alanylaminobenzyl, phenylamino, carbamoyl, phenoxy or cycloalkyl; or R_5 is a group of the following formula:



and physiologically acceptable salts of said nucleoside derivative. --

-- 15. The method of Claim 11, wherein said A_3RAg is N^6 -2- (4-aminophenyl)ethyladenosine (APNEA), N^6 -(4-amino-3-iodobenzyl) adenosine- 5'-(N-methyluronamide) (AB-MECA), N^6 -(3-iodobenzyl)-adenosine-5'-N- methyluronamide (IB-MECA), or 2-chloro- N^6 -(3-iodobenzyl)-adenosine-5'-N-methyluronamide (Cl-IB-MECA).-- .

Authorization for this Examiner's Amendment was given in a telephone interview with Allen Yun on December 5, 2007.

The following is an Examiner's Statement of Reasons for Allowance:

Examiner notes the submission of additional prior art and has considered same, but has not found any disclosure or disclosures that individually or in combination with prior art of record justify the assertion of either an obviousness rejection or an anticipation rejection. The newly submitted references are now of record on the current PTO-892 attached hereto.

Examiner notes applicant's amendments filed October 2, 2007 and the amendments agreed to above. These amendments taken together have effectively addressed the issues outstanding in this case and have rendered same moot. Therefore, the instant claims as presently amended have been found to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

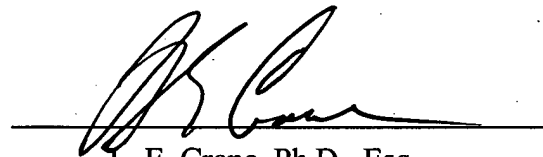
All Post-Allowance Correspondence concerning this application must be mailed to:
BOX ISSUE FEE

COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

OR you can FAX them to the Office of Patent Publications at 571-273-8300, in order to expedite the handling of such correspondence as amendments under 37 C.F.R. §1.312; Information Disclosure Statements (IDS's), and formal drawings. Sending Post-Allowance

papers to Technology Center 1600 will only cause delays in matching papers with the case. For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at 571-272-4200. The Notice of Allowance also has an insert containing contact information for other items, including Issue Fees, receipt of formal drawings, and the status of the application.

LECrane:lec
12/05/2007

A handwritten signature in black ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600